K110865

SECTION 5

APR 27 2011

510(k) SUMMARY
Summary of Safety and Effectiveness information

Tornier Inc. Aequalis Ascend Modular Anatomic Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) **Device name**

Trade name: **Aequalis Ascend Modular Anatomic Shoulder System**
Common name: Shoulder Prosthesis
Classification Number/ Classification name/Product code:

- Shoulder joint, humeral (hemi-Shoulder), metallic uncemented prosthesis are class II devices under 21 CFR 888.3690 (product code HSD) and are classified by the Orthopedic Devices Panel

- Shoulder joint metal/polymer non-constrained cemented prosthesis are class II devices under 21 CFR 888.3650 (product code KWT) and are classified by the Orthopedic Devices Panel

- Shoulder joint metal/polymer semi-constrained cemented prosthesis are class II devices under 21 CFR 888.3660 (product code KWS) and are classified by the Orthopedic Devices Panel

2) **Submitter**

Tornier Inc.
7701 France Avenue South; Suite 600
Edina, MN 55435
Registration Number: 9100540

3) **Company contact**

Brahim Hadri
Sr. Regulatory affairs Specialist
100 Cummings Center, Suite 444C,
Beverly, MA 01915, U.S.A
Phone: 1 978 232-9997 ext: 617
Fax: 1 978-232-9998
bhadri@tornier.com

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4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	**HSD; KWT; KWS**

5) **Legally Marketed Device to which Equivalence is Claimed:**

- Tornier Inc. Aequalis Ascend Modular Anatomic Shoulder System K102924

6) **Device description**

The Aequalis Ascend Modular Anatomic Shoulder system is supplied in separate sterile packages which will be assembled in the operating room. The system is comprised of the following components:

- The Modular Distal Stem
- The Modular Anatomic Metaphysis
- The Modular Anatomic Assembly Screw.

This assembly will mate with existing; FDA cleared Tornier Ascend Monolithic Humeral Heads (K071147) which were designed to articulate with FDA cleared Tornier Aequalis and Affiniti Glenoid replacements (K063081 and K060988 respectively).

This submission corresponds to a change made to the **Aequalis Ascend Modular Anatomic Shoulder System** (previously cleared in 510(k) K102924).

7) **Materials**

- The Modular Distal Stem and Modular Anatomic Metaphysis components are manufactured from Titanium according to ASTM F 136 Standard Specification for Wrought Titanium - 6Aluminum - 4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

- The Modular Anatomic Assembly Screw is manufactured from Cobalt Chromium Molybdenum alloy according to ASTM F-1537 Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants

    - The Modular Anatomic Assembly Screw includes an Ultra High Molecular Weight Polyethylene (UHMWPE) plug to prevent loosening. The material of the screw is accordance to ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants or ISO-5834-2. Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 2: Moulded forms

8) **Indications for Use**

- The Aequalis Ascend Modular Anatomic Shoulder System is indicated for use as a replacement of Shoulder joints disabled by:
    - Rheumatoid arthritis with pain
    - Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
    - Correction of functional deformity
    - Fractures of the humeral head
    - Traumatic arthritis

    Notes:

    - All components are single use
    - The humeral stem is intended for cemented or cementless use
    - The glenoid component is intended for cemented use

9) **Summary of technologies**

The modifications made to the proposed Tornier Aequalis Ascend Modular Anatomic Shoulder System were verified and validated by performing bench testing. The results of the testing allow us to conclude that the proposed Aequalis Ascend Modular Anatomic Shoulder System described in this submission does not induce any new or higher risk compared to the predicate device and therefore both device (proposed and predicate) are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tornier, Inc.
% Mr. Brahim Hadri
Senior Regulatory Affairs Specialist
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

APR 2 7 2011

Re: K110865
Trade/Device Name: Aequalis® Ascend™ Modular Anatomic Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT, HSD
Dated: March 25, 2011
Received: March 29, 2011

Dear Mr. Hadri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must,

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110865

Device Name: **Aequalis® Ascend™ Modular Anatomic Shoulder System**

Indications for Use

- The Aequalis Ascend Modular Anatomic Shoulder System is indicated for use as a replacement of Shoulder joints disabled by:
    - Rheumatoid arthritis with pain
    - Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
    - Correction of functional deformity
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    - Traumatic arthritis

    Notes:
    - All components are single use
    - The humeral stem is intended for cemented or cementless use
    - The glenoid component is intended for cemented use

Prescription Use ____X_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110865

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